ADAPTIVE NEUROMODULATION IN THE TREATMENT OF SPASTICITY

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ABSTRACT

This research has the purpose to evaluate the immediate effects on spasticity of lower limbs of a single session of two different therapeutic approaches in patients affected by cerebral palsy.
A total of 30 patients, with an age between and 10-40 years old and affected by cerebral palsy associated to spastic para/tetra paresis, were recruited and equally and randomly divided into 3 groups: group A has was treated with hydrokinesitherapy (HKT). Group B was treated with adaptive electro neuromodulation (ENM). Group C underwent a sham approach respecting the operative procedure of Group B with the device not operating.
All patients were evaluated, before (T0) and after (T1) the single session of treatment, through myometric evaluation of muscular rheological parameters.
The analysis of results underlined that both HKT and ENM resulted effective in reducing muscular hypertone associated to spasticity, while in Group C no significant results were detected.
We can affirm that both ENM and HKT approach can be good alternatives for the treatment of spasticity in patients affected by cerebral palsy.

INTRODUCTION

Cerebral palsy describes a group of disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or by a seizure disorder (Bax et al., 2005).
The natural history of cerebral palsy is gradually worsening. If no intervention is taken, changes in gait and function are not conducive. Eventually, muscle contracture, joint stiffness, gait instability, bone deformity, scoliosis, subluxation or dislocation of the hip joint, deformity of the long bones, or malformation of the foot may occur (Lin et al., 2018).
Global cerebral palsy prevalence has remained stable at about 2 to 3 per 1000 for several decades, even if today there is a better clinical management of newborns, whether they are term or preterm (Clark & Hankins, 2003).
The treatment varies from progressive resistance training to active exercise and passive movement, muscle strength training, stretching, balance, and gait training, to more complex functional tasks. A wide range of outcome measures are described in literature. Frequently used parameters in children with cerebral palsy are: spasticity, ROM, muscle strength, energy cost, gait parameters, gross motor function, walking scales, and quality of life, modified Ashworth scale (MAS), and ROM of the knee, hip, ankle using and goniometers (Van Bommel et al., 2019).
The current treatment methods for relieving muscle spasms, that are one of the most common and disabling manifestation of the pathology include exercise therapy, physical therapy, rehabilitation in aquatic environment and traditional rehabilitation therapy. The application of botulinum toxin, surgery, and brace is also a good way to relieve muscle spasms. However, a single treatment does not guarantee absolute effectiveness. Therefore, rehabilitation requires comprehensive treatment, and parents and rehabilitation workers are still looking forward to finding more treatments that can effectively relieve muscle spasms (Lin et al., 2018).
It is known in literature that in the presence of a somatic dysfunctional condition, the skin shows a proper impedance value that represents the autonomic expression of the dysfunction itself (Barassi et al., 2019).
In the past, several structural and functional studies on the skin have used bioelectric and biochemistry property measurements to evaluate the state of health of the muscle tissues (deVires, 1969).
However, this approach did not provide enough specific analytical and functional information to predict statistically significant electrical behaviour of the skin and, as a result, to determine what kind of treatment would obtain a specific muscle tone rebalance.
It is known that the characteristics of material conductivity and dielectrics, including biological tissue, show frequencies dispersion (Van Loan et al., 1993).
The impedance shows a complex resistivity (real and imaginary) displayed under alternating Current (Foster & Lukaski, 1996).
It is possible to shape the electrical impedance of body tissues, associated to a postural condition, and their rheological muscular characteristics, describing the bio impedance potentiality of the human skin trough tests and treatments in patients through adaptive or interactive electro neuromodulation (ENM) (Martinsen & Grimnes, 2011; Yamamoto & Yamamoto, 1986).

This is a form of electrotherapy characterized by biphasic damped sinusoidal signals variable in time, with morphological characteristics like ECG. The approach also features a potential action of high amplitude, short and not harmful, avoiding the adaptation process of the body thanks to the feedback that always generates different signals depending on the skin impedance alterations detected.

The passive electrical properties of the human skin have been studied through the "Cole mathematic method" using bio impedance measurements under 100 kHz .Cole's model covers both the conductive and dielectric properties, while the approach mainly describes the dielectric characteristics (defined as permittivity). The skin, as a complex organ of ectodermal embryological derivation, shows both dielectric and conductive behaviours, and this new therapeutic approach can be applied to describe and precisely study the bioimpedance properties of this organ, both in the evaluative and in the therapeutic fields (Cole, 1940).

Biological membranes show a high, non-conductive capacity and a complicated model of low conductivity. Biological tissues, as a complex multi-layered system, behave as an anisotropic material following the variable orientation of cells and their plasmatic membranes. Since 1940, Cole has hypothesized a mathematic model taking care of the bioelectrical properties of the cell's membranes, based on impedance measurements with a multi-frequency, alternated current (Cole, 1940). In the presence of a somatic dysfunctional condition, the skin shows a proper impedance value that represents the autonomic expression of the dysfunction itself.

Basing on these considerations, to identify the real therapeutic potential of ENM, we decided to perform a study on the efficacy of ENM, compared to hydrokinesitherpy (HKT) and a sham ENM treatment (SHAM), in the management of spasticity associated to cerebral palsy.

METHODS AND MATERIALS

In the Physiotherapy Center of Rehabilitation and Reeducation (Ce.Fi.R.R.) located at the premises of the University "Gabriele d'Annunzio" of Chieti-Pescara, it has been performed a study to verify the efficacy of ENM compared to HKT and SHAM in the management of spasticity associated to cerebral palsy. All participants gave written informed consent to the experimental procedure, which was in accordance with the latest revision of the Declaration of Helsinki and the procedures defined by ISO 9OO1 standards for "Research and Experimentation"; this procedure also protects the privacy of subjects participating in biomedical research.

A total of 30 patient, affected by spasticity connected to tetra/para paresis associated to cerebral palsy, with a Ashwort Scale Score between 1 and 3 a age between 10 and 40 years old, were selected and randomized into three groups of treatment. Group A (n=10) underwent treatment with HKT, group B (n=10) underwent treatment with ENM and group C (n=10) underwent SHAM.

Exclusion criteria were the presence of cardiovascular pathologies and the execution of botulinum toxin treatment or surgical intervention to modify tendons length.

Patients has been evaluated at time T0 (before starting the session) and time T1 (after the end of the session) through myometric evaluation of muscular rheological parameters through the system Myoton Pro (Myoton AS©, Tallin, Estonia) (Peipsi et al., 2012). This instrument is characterized by a non-piercing needle pointer, which mechanically hit the surface of the desired bodypart to detect the rheological properties of the desired superficial muscles, in terms of tone (defined as "F = frequency", expressed in Hz), elasticity (defined as "D = logarithmic decrement", expressed as a pure number) and stiffness (defined as "S = stiffness" or tissue resistance, expressed in N/m).

Measurements were performed on the gastrocnemius muscle, indicated by many as the main spasticity indicator in patients affected by cerebral palsy (Pollock, 1953). Each single measurement was performed in the same room, to guarantee the maximum constancy of ambient conditions.

Patients of group A were treated with a single session of HKT. The treatment taked advantage of the hydrostatic force of water ambient to stabilize the posture and reduce the influence of gravity on treated patients. Moreover, the physical overload opposed to movements by water is far gentler and easier to manage compared to what is normally performed in a dry ambient. It is also important to consider that a water temperature over 30°, like the one of the waters used for the protocol, can induce a general muscular relaxation in the human body. The protocol used for the single session of HKT was the following:

- presession stretching of lower limbs on a bed out of the water;
- acclimatization and flotation in water supported by tubular tools in high water;
- walking in low water with the support of the therapist;
- walking in low water with the support of plantar proprioceptive tablets;
- position changes in water;
- leg exercises in water leaned on a support bar;
- swimming backstroke with the support of a lumbar tablet proprioceptive;
- lumbar side pendulum with the support of the therapist.
- The single session of HKT lasted a total of 60 minutes.

Patients of group B were treated with a single session of ENM, applied through the system ENF Physio (Fast Therapies S.r.l.©, Carpenedolo, Brescia, Italia) (Barassi et al., 2019). The device, obtaining cutaneous impedance information, modifies continuously the amount and fundamental parameters of the electrical current delivered, modulating it consequently to the tissue treated response. The electrical wave form is biphasic sinusoidal with a range of frequency of about 15- 350 Hz.

The therapy was applied using "deep drainage" program, applying the two electrodes of the device one on each gastrocnemius muscle.

The session of ENM lasted a total of 20 minutes.

Patients of group C were treated with a single session of SHAM, consisting of a simulated application of ENM with the exact same procedure applied for group B but with the device set in order not to provide the electrical stimulation.

RESULTS

The quantitative analysis of collected data was performed using the Office Excel software (Microsoft®, Redmond, Washington, USA), through which it was possible to realize the graphic representation of the mean variance of tone (F), elasticity (D) and stiffness (S) of the gastrocnemius muscle, considered also a mean of both left and right gastrocnemius.

Moreover, using the statistical analysis software NCSS Data Analysis 9 (NCSS© LLC, Kaysville, UT, USA), it was possible to evaluate the significance of results obtained, using the Wilcoxon Signed-Rank T-Test.

The quantitative analysis of the variance of shows that some changes of myometric parameters occurred during the study, especially in groups A and B. In terms of muscular tone group A and B highlighted a clear reduction of tone from before to after the interventions (Figure 1). The SHAM group C on the contrary showed a slight increase of the tone after the intervention (Figure 1).

Looking at the elasticity it is possible to see how no major changes occurred regarding this parameter, with only group A showing a minimal increase of the value of D (Figure 2).

Finally, talking about muscular stiffness, is possible to see how only group A and B showed a reduction of muscular stiffness after the intervention, with group A obtaining a slightly greater reduction then group B (Figure 3). Group C showed almost no changes at all in term of muscular stiffness of the gastrocnemius (Figure 3).

From a statistical standpoint reductions obtained for muscular tone resulted significant both in groups A and B ($p<0,05$), while the reduction of stiffness resulted significant only for group A ($p<0,05$) (Figures 4.1, 4.2 and 5).

DISCUSSION

Results of this study were generally positive, both confirming the efficacy of HKT and highlighting the possible viability of ENM as treatments of the spasticity associated to cerebral palsy.

Regarding HKT is possible to say that floatability is the main physical property of water responsible for the postural support and reduction of physical overload, allowing even children with cerebral palsy to move independently (Kelly & Darrah, 2005). Float-

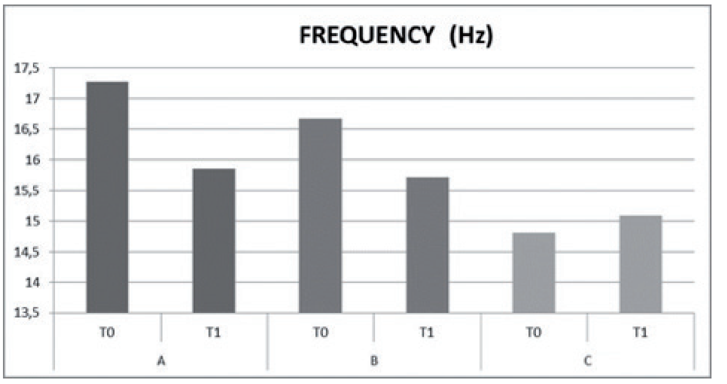

Fig. 1 - Mean variation of muscular tone (Frequency) of the gastrocnemius muscles in groups A, B and C.

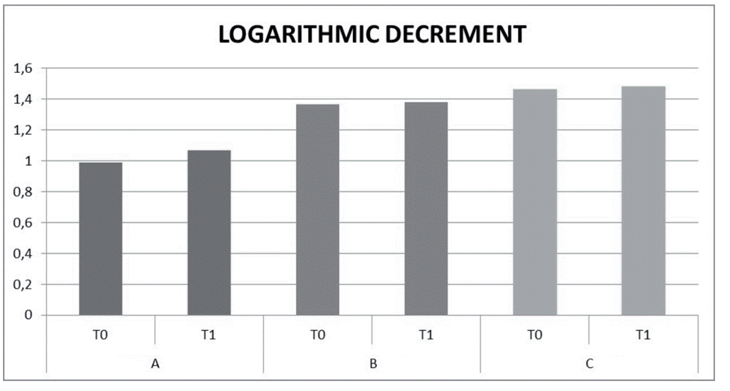

Fig. 2 - Mean variation of muscular elasticity (Logarithmic Decrement) of the gastrocnemius muscles in groups A, B

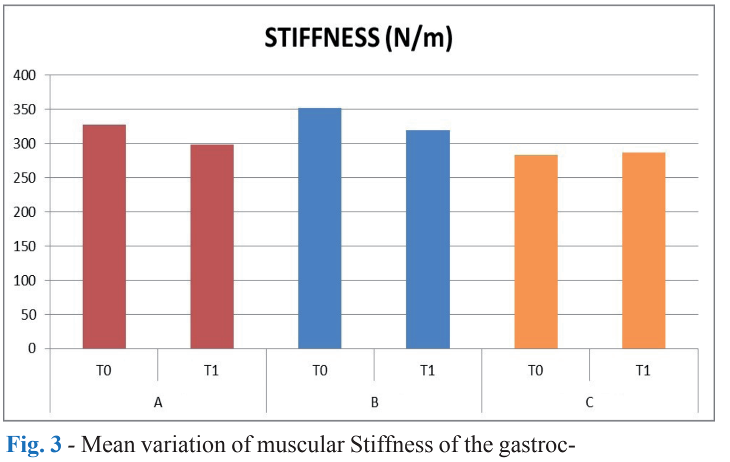

Fig. 3 - Mean variation of muscular Stiffness of the gastrocnemius muscle in groups A, B and C.

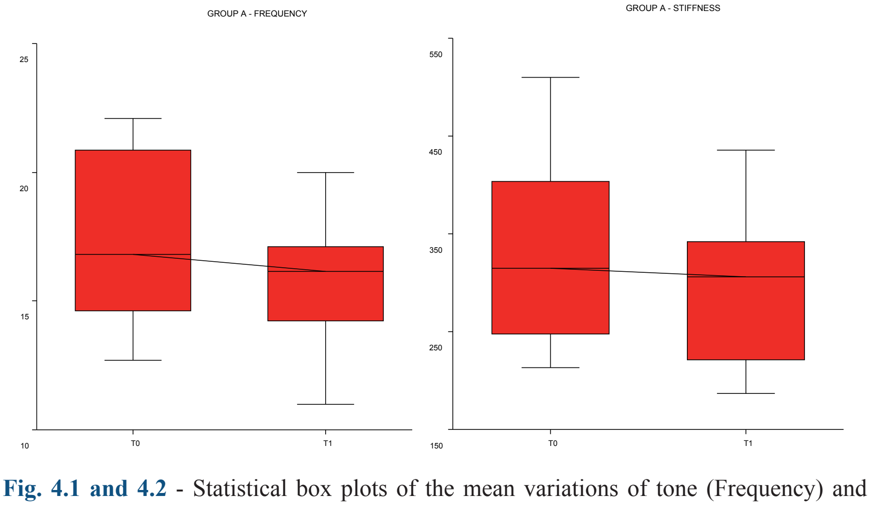

Fig. 4.1 and 4.2 - Statistical box plots of the mean variations of tone (Frequency) and Stiffness in group A (HKT).

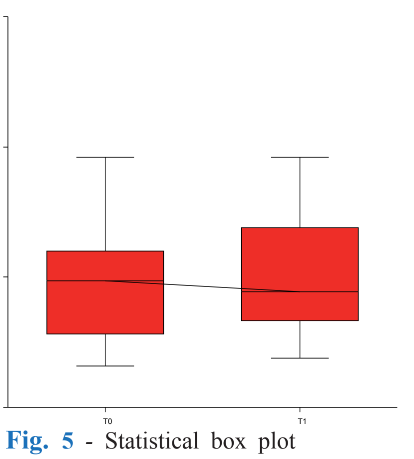

Fig. 5 - Statistical box plot of the mean variations of tone (Frequency) in group B (ENM).

ability is a force that helps in sustaining and maintaining movements in water (Irion, 2009). It has been proven that working in water environment is a very important thing for a lot of neurologic conditions such as cerebral palsy, spinal paraplegia and amputations (Prins, 2009). It is also important to notice that the water environment is important also to reinforce the self-belief of patients and is a rehabilitative and recreative environment suitable for people of all ages (Daly & Lambeck, 2007; Lepore, 2005).

Speaking about ENM is possible, on the basis of the results obtained, that the somatic stimulation provided by this kind of therapy is able to actually influence the functionality of a specific area, even if affected by a central nervous system dysfunction like in cerebral palsy.

It was previously demonstrated that this kind of application is able to determine a kind of therapeutic effect that is not only local or limited to the peripheral site of the dysfunction but actually working on more complex physiological pathways, probably involving the activation and responses of the central nervous system, like for example in terms of pain sensitivity (Oteri et al., 2018) and in terms of muscular rheological status (Barassi et al., 2019; Bellomo et al., 2016). Regarding the ENM approach is important to highlight that this kind of approach is quite simple in terms of pure application as well as relatively cheap in terms of time and cost of the treatment, which is an important factor to consider when talking about cerebral palsy, which is characterized by an urgent request of new, simple and effective approaches of treatment to increase the ability to manage a so invalidating condition in clinical practice (Papavasiliou, 2009).

CONCLUSIONS

Results of this study confirmed the efficacy of HKT and highlighted the potential utility of ENM for the management of spasticity related to cerebral palsy.

It will be interesting, for the future, to continue exploring the therapeutic possibilities of the ENM application in the field of neurologic pathologies, especially those like cerebral palsy, possibly setting new studies with a longer duration, middle and long term follow-ups, wider samples, deeper evaluations and other more strict setting criteria.

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